

# PDA Advanced Therapy Medicinal Products Conference 2026

## Agenda



### Thursday, 25 June

CEST Daylight Time (UTC +2:00)

#### Welcome and Introduction

09:00 – 09:10

**Committee Member:** Falk Klar PhD, General Manager, Vice President Europe, *Parenteral Drug Association*

#### Welcome from the Co-Chairs

09:10 – 09:20

**Co-Chair:** Ryan Murray MS, Senior Consultant, *ValSource, Inc.*

**Co-Chair:** Rebecca D. Jordan Director, Global Cell Therapy Sterility Assurance Lead *Bristol Myers Squibb*

#### Opening Session: Regulatory Horizons in The Age of Intelligence

**Moderator:** Ryan Murray MS, Senior Consultant, *ValSource, Inc.*

##### Japan's Standards for Raw Materials Used in ATMPs

09:20 – 09:45

- **Regulatory Presenter:** Yoji Sato , ,

09:45 – 10:10

**Title to be announced**

##### Manufacturing ATMPs in the EU: Regulatory Perspectives and Challenges

09:20 – 11:15

10:10 – 10:35

- **Regulatory Presenter:** Roberto Conocchia MD, GMP Technical Lead, *European Medicine Agency*

##### Q&A and Discussion

10:35 – 11:15

- **Moderator:** Ryan Murray MS, Senior Consultant, *ValSource, Inc.*
- **Panelist:** Yoji Sato , ,
- **Panelist:** Roberto Conocchia MD, GMP Technical Lead, *European Medicine Agency*

11:15 – 11:45

**Networking Coffee Break, Poster Session & Exhibition**

#### Session 1: Automation, Robotics & Digital Transformation in Cell and Gene Therapy Manufacturing

**Moderator:** Richard Denk , Senior Consultant Aseptic Processing, *SKAN AG*

##### Modular and Robotic Process for Cell Therapy Manufacturing

11:45 – 12:05

- **Co-Presenter:** Fabio Dondi MSc Mechanical Engineering, R&D Manager, *Fedegari*
- **Co-Presenter:** Alice Melocchi PhD, Associate Professor; Chief Scientific Officer, *Università degli Studi di Milano; Multiply Labs, Inc.*

##### Pipettes, Pixels, and Pipelines – Making Cell Therapy Automation Approachable

	12:05 – 12:25	<ul style="list-style-type: none"> <li>• <b>Presenter: Anne Baldwin</b> , Principle Automation Engineer, <i>Genentech</i></li> </ul>
11:45 – 13:15		<b>Title to be announced</b>
	12:25 – 12:45	<ul style="list-style-type: none"> <li>• <b>Academic Presenter: Ines Groß-Weege MSc</b>, Research Fellow, <i>Fraunhofer Institute for Production Technology</i></li> </ul>
		<b>Q&amp;A and Discussion</b>
		<ul style="list-style-type: none"> <li>• <b>Moderator: Richard Denk</b> , Senior Consultant Aseptic Processing, <i>SKAN AG</i></li> <li>• <b>Panelist: Riccardo Masili</b> , ,</li> </ul>
	12:45 – 13:15	<ul style="list-style-type: none"> <li>• <b>Panelist: Alice Melocchi PhD</b>, Associate Professor; Chief Scientific Officer, <i>Università degli Studi di Milano; Multiply Labs, Inc.</i></li> <li>• <b>Panelist: Anne Baldwin</b> , Principle Automation Engineer, <i>Genentech</i></li> <li>• <b>Panelist: Ines Groß-Weege MSc</b>, Research Fellow, <i>Fraunhofer Institute for Production Technology</i></li> </ul>

	<b>LIVE Guided Poster Walk</b>
13:15 – 13:45	<b>Moderator: Josh Eaton MS</b> , Senior Director, Scientific and Regulatory Affairs, <i>PDA</i>

13:30 – 14:45	<b>Networking Lunch Break, Poster Session &amp; Exhibition</b>
---------------	--

	<b>Session 2</b>	
	<b>Moderator: Claudia Lee PhD</b> , VP of R&D, <i>Velvet Therapeutics</i>	
	<b>Development and Validation of a Dual-Purpose NGS Platform for rAAV Identity and Variant Detection Testing</b>	
	14:45 – 15:05	<ul style="list-style-type: none"> <li>• <b>Presenter: Megan Gura PhD</b>, Principal QC Virology Scientist, <i>Regeneron Pharmaceuticals, Inc.</i></li> </ul>
	<b>Advancements in QC Microbiology Automation &amp; Digitalization</b>	
	15:05 – 15:25	<ul style="list-style-type: none"> <li>• <b>Presenter: George Bouras MSc, MBA</b>, Commercial Application Manager Automation &amp; Robotics - EMEA, <i>Merck</i></li> </ul>
14:45 – 16:15	<b>Navigating Practical Challenges in Replication-Competent Lentivirus (RCL) Testing to Ensure Regulatory Compliance</b>	
	15:25 – 15:45	<ul style="list-style-type: none"> <li>• <b>Presenter: Anna Woodward PhD</b>, Technical Consultant, <i>Merck</i></li> </ul>
	<b>Q&amp;A and Discussion</b>	
	15:45 – 16:15	<ul style="list-style-type: none"> <li>• <b>Moderator: Claudia Lee PhD</b>, VP of R&amp;D, <i>Velvet Therapeutics</i></li> <li>• <b>Panelist: Megan Gura PhD</b>, Principal QC Virology Scientist, <i>Regeneron Pharmaceuticals, Inc.</i></li> <li>• <b>Panelist: George Bouras MSc, MBA</b>, Commercial Application Manager Automation &amp; Robotics - EMEA, <i>Merck</i></li> <li>• <b>Panelist: Anna Woodward PhD</b>, Technical Consultant, <i>Merck</i></li> </ul>

16:15 – 16:45	<b>Networking Coffee Break, Poster Session &amp; Exhibition</b>
---------------	---

	<b>Session 3: Operational Excellence for ATMPs: Optimizing Shop Floor Execution</b>
	<b>Moderator: Ola Adel MA</b> , Site Quality Head Aseptics and Cell and Gene Therapy , <i>Novartis</i>

16:45 – 17:50	16:45 – 17:00	<b>Advancing rAAV Manufacturing: Leveraging Platform Processes &amp; Agile Development Tools</b> <ul style="list-style-type: none"> <li>• <b>Presenter: Hannah Seo PhD</b>, Principal Scientist, <i>Bristol Myers Squibb</i></li> </ul>
	17:00 – 17:20	<b>Operationalizing Lab-in-the-Loop for iPSC Cell Therapy Development</b> <ul style="list-style-type: none"> <li>• <b>Presenter: Ro DeJesus MPH</b>, Senior Scientific Manager, <i>Genentech</i></li> </ul>
	17:20 – 17:50	<b>Q&amp;A and Discussion</b> <ul style="list-style-type: none"> <li>• <b>Moderator: Ola Adel MA</b>, Site Quality Head Aseptics and Cell and Gene Therapy , <i>Novartis</i></li> <li>• <b>Panelist: Hannah Seo PhD</b>, Principal Scientist, <i>Bristol Myers Squibb</i></li> <li>• <b>Panelist: Ro DeJesus MPH</b>, Senior Scientific Manager, <i>Genentech</i></li> </ul>
17:50 – 17:50	<b>End of Conference Day 1 &amp; Networking Event</b>	

## Friday, 26 June

CEST Daylight Time (UTC +2:00)

09:00 – 09:05	<b>Welcome Back by the Co-Chairs</b>	
	<b>Co-Chair: Rebecca D. Jordan</b> , Director, Global Cell Therapy Sterility Assurance Lead, <i>Bristol Myers Squibb</i> <b>Co-Chair: Ryan Murray MS</b> Senior Consultant <i>ValSource, Inc.</i>	
<b>Session 4: Contamination Strategies in ATMP Manufacturing</b>		
<b>Moderator: Judith Koliwer PhD</b> , Senior Industry Advisor & Principal Consultant Advanced Therapies, <i>Körber Pharma Software</i>		
09:05 – 10:25	09:05 – 09:25	<b>A Novel Risk-Based Strategy to Enhance Airflow Visualization Studies (AVS)</b> <ul style="list-style-type: none"> <li>• <b>Co-Presenter: Tiffany A. Baker MBA</b>, Senior Consultant, <i>ValSource, Inc.</i></li> <li>• <b>Co-Presenter: James Wamsley</b> , Consultant, <i>ValSource, Inc.</i></li> </ul>
	09:25 – 09:35	<b>Title to be announced</b> <ul style="list-style-type: none"> <li>• <b>Presenter: Claudia Lee PhD</b>, VP of R&amp;D, <i>Velvet Therapeutics</i></li> </ul>
	09:35 – 09:55	<b>Barrier Technologies and Contamination Control Strategies for ATMP Manufacturing under GMP</b> <ul style="list-style-type: none"> <li>• <b>Co-Presenter: Birte Scharf PhD</b>, Senior Scientist GMP Compliance, <i>Franz Ziel GmbH</i></li> <li>• <b>Co-Presenter: James Lindsay Drinkwater</b> , Head of GMP compliance, <i>Franz Ziel GmbH</i></li> </ul>
	09:55 – 10:25	<b>Q&amp;A and Discussion</b> <ul style="list-style-type: none"> <li>• <b>Moderator: Judith Koliwer PhD</b>, Senior Industry Advisor &amp; Principal Consultant Advanced Therapies, <i>Körber Pharma Software</i></li> <li>• <b>Panelist: Tiffany A. Baker MBA</b>, Senior Consultant, <i>ValSource, Inc.</i></li> <li>• <b>Panelist: James Wamsley</b> , Consultant, <i>ValSource, Inc.</i></li> <li>• <b>Panelist: Claudia Lee PhD</b>, VP of R&amp;D, <i>Velvet Therapeutics</i></li> <li>• <b>Panelist: Birte Scharf PhD</b>, Senior Scientist GMP Compliance, <i>Franz Ziel GmbH</i></li> </ul>

10:25 – 10:55 **Networking Coffee Break, Poster Session & Exhibition**

**Session 5: Lifecycle Risk Management**

**Moderator: Lori Dingleline** , QC Lead- Microbial Control and Compendial Testing, *Spark Therapeutics, Inc.*

10:55 – 12:25

**Hybrid ATMP and Digital Delivery Systems: Regulatory Challenges and Global Considerations**

10:55 – 11:15

- **Academic Presenter: Afrah Mujeeb AM**, Regulatory Affairs Specialist, *FDA Blueprint*

11:15 – 11:35

**From Guideline to Practice: Temperature Excursion Management**

- **Presenter: Milena Opacic PhD**, Principal Scientist II, *Johnson&Johnson*

11:35 – 11:55

**Timing for Implementation of GMP Raw Materials for ATMPs**

- **Presenter: Rachael Atlee** , VP Operations, *Akron Bio*

11:55 – 12:25

**Q&A and Discussion**

- **Moderator: Lori Dingleline** , QC Lead- Microbial Control and Compendial Testing, *Spark Therapeutics, Inc.*
- **Panelist: Afrah Mujeeb AM**, Regulatory Affairs Specialist, *FDA Blueprint*
- **Panelist: Milena Opacic PhD**, Principal Scientist II, *Johnson&Johnson*
- **Panelist: Rachael Atlee** , VP Operations, *Akron Bio*

12:25 – 13:25 **Networking Lunch Break, Poster Session & Exhibition**

**Interactive Session**

13:25 – 14:25

**Moderator: Francesco Cicirello PharmD, MSc**, Senior Director Global BioNTainer Quality Compliance, *BioNTech US*

14:25 – 14:55 **Networking Coffee Break, Poster Session & Exhibition**

**Passport Raffle**

14:55 – 15:00

**Moderator: Melanie Decker** , , *Parenteral Drug Association*

15:00 – 15:05 **Best Poster Presentation**

**Closing Session**

**Moderator: Rebecca D. Jordan** , Director, Global Cell Therapy Sterility Assurance Lead, *Bristol Myers Squibb*

15:05 – 15:25

**Fireside Chat**

- **Regulatory Presenter: Christina Meissner PhD**, Group Manager, *AGES - Austrian Agency for Health and Food Safety GmbH*
- **Co-Presenter: Richard Denk** , Senior Consultant Aseptic Processing, *SKAN AG*

15:05 – 16:15

15:25 – 15:45

**Title to be Announced**

- **Regulatory Presenter: Ilona Reischl-Kok PhD**, Assessor, *Austrian Medicines and Medical Devices Agency (AGES MEA)*

**Q&A, Discussion**

- **Moderator: Rebecca D. Jordan** , Director, Global Cell Therapy Sterility Assurance Lead, *Bristol Myers Squibb*

15:45 – 16:15

- **Panelist: Christina Meissner PhD**, Group Manager, *AGES - Austrian Agency for Health and Food Safety GmbH*
- **Panelist: Ilona Reischl-Kok PhD**, Assessor, *Austrian Medicines and Medical Devices Agency (AGES MEA)*

**Co-Chairs Conference Summary**

16:15 – 16:25

**Co-Chair: Rebecca D. Jordan** , Director, Global Cell Therapy Sterility Assurance Lead, *Bristol Myers Squibb*

**Co-Chair: Ryan Murray MS** Senior Consultant *ValSource, Inc.*

**Closing Remarks & Farewell**

16:25 – 16:30

**Committee Member: Falk Klar PhD**, General Manager, Vice President Europe, *Parenteral Drug Association*

16:30 – 16:30

**End of Conference**